properties, radioopacity, transverse geometric profile of the endoluminal stent, Z-axis thickness, X-Y-axis surface area of the first and second structural elements, thereby affecting at least one of longitudinal flexibility, hoop strength, radial expansion behavior and profile of the endoluminal stent.

Summary of Amendments

Applicants have amended Claims 17-22 to correct dependencies between claims and traverse the Examiner's basis for Objection under 37 C.F.R. 1.75(c). Based upon the Examiner's Interview of October 3, 2002, new claims 29-37 have been introduced to more narrowly define the invention with reference to a particular substrate configuration ("a generally continuously curved exterior surface"), positively reciting the stent-forming step (c) and the formation of the structural elements of the stent and positively reciting that the endoluminal stent is capable of radial expansion by geometric deformation of at least some of the second (circumferential) structural elements in new step (d). Antecedent support under 35 U.S.C. §112, second paragraph for these amendments to Claim 29 may be found in the specification as originally filed at Page 17, lines 1-8 (describing geometric deformation of the second structural elements during radial expansion), Page 13, lines 21-22 (the substrate may be cylindrical, *i.e,* having an exterior surface with a continuous curve), and Pages 15-26 (describing the first and second structural elements, generally). The antecedent support under 35 U.S.C. §112, second paragraph, for new claims 35-38 may be found at Pages 10, line 6 to Page 11, line 10 and Pages 14-15. The antecedent support for Claims 30-34 is found in the originally filed claims and specification.

Remarks

The originally-filed claims were restricted into two groups of inventions: Group I (claims 1-13 and 24-28) drawn to a stent structure and Group II (claims 14-23) drawn to a method of making a stent by vacuum deposition.

Applicants thank Examiner for the telephone conversation with the Applicants' attorney, David Rosenbaum on March 25, 2002. In this conversation, Mr. Rosenbaum made a provisional election to prosecute the invention of Group II (claim 14-23). This election is hereby affirmed.

Applicants maintain the right to prosecute the invention of Group I by filing a divisional application.

Applicant's also gratefully acknowledge the time and efforts of the Examiner and SPE Bruce Snow during the Examiner's Interview held October 3, 2002. The Examiner's Interview Summary Record faxed to the undersigned attorney-of-record on October 3, 2002 is gratefully acknowledged.

I. The Rejection of Claims 14-23 under 35 U.S.C. 102 over either Roth (US Patent No. 6,096,175), Moller et al. US Patent No. 5,772,864) or Reed et al. (US Patent No. 6,197,013) Should be Withdrawn.

Anticipation under 35 U.S.C. §102 requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). *In re Robertson,* 49 USPQ2d 1949 (Fed. Cir. 1999). The rejection of claims 14-23 under section 102 over at least one of the following references: Roth, Moller and Reed, should be withdrawn because the references fail to disclose every element of claims 14-23 individually and, therefore, fail to anticipate the claimed invention.

The Patent Office incorrectly states in the office action that Roth discloses all elements of independent claim 14, let alone the claims that depend from claim 14 (claims 15-23), in supporting its 102(e) rejection. Since Roth fails to disclose every element it cannot anticipate the present invention. Among the reasons why Roth fails to anticipate the claimed invention is that Roth fails to disclose the fabrication of a stent that is radially expansible or "capable of radially expanding" (as claim 14 recites). In item 9 of the Office Action, the Examiner alleges that Roth discloses this element on Col. 2, lines 22-24, but this section only recites, as part of the background, that "many significant aneurysms take place in the Circle of Willis and approaching blood vessels." The apparatus disclosed in Roth is referred to as "**rolled sheet** stents" (emphasis added). Roth, col. 3, line 16. Furthermore, Roth explains in the detailed description section that the stent is formed so that "when rolled and released, it resiliently unrolls and expands to . . ." Roth, col. 4, lines 30-34. This description is of a rolled sheet that increases diameter by simply unraveling or reducing the amount of overlap of the sheet. This is not the radial expansion that is

an element of the claimed invention. . In Roth, the diametric change of the rolled stent is not the result of any geometric shape change in the rolled sheet, itself. This is not the radial expansion that is an element of the claimed invention. The claimed invention is a closed cylindrical stent, which when undergoing expansion expands radially outward. Accordingly, Roth fails to anticipate the claimed invention.

In sharp contrast to Roth, the present claims recite stents "capable of radially expanding," which is well known in the implantable medical device arts to mean a device that undergoes a diametric change because of a geometric change or deformation by either plastic, elastic, shape memory or pseudoelastic deformation. Since there is no geometric change or deformation of the rolled sheet stent in Roth, one skilled in the art would understand that the rolled sheet stent is **not** "capable of radially expanding."

The rejection of claims 14-17 and 21 under section 102(b) over Moller et al should be withdrawn because it fails to disclose all the elements of the claimed invention. Since Moller et al. fails to disclose every element it cannot anticipate the present invention. Moller et al. fails to anticipate the claimed invention because while disclosing methods of forming a metallic stent, Moeller et al. fails to disclose methods that include vacuum deposition. The Examiner incorrectly alleges that Moller et al. discloses deposition by vacuum deposition. In particular, the Examiner points to various sections of the specification in Moller et al., but none of the cited sections discloses vacuum deposition. Col. 3, lines 30-31 and 44-48 only generally discusses deposition of material into the reverse image of the mandrel. Whereas, col. 4, lines 38-40 discusses a specific deposition method, electro-deposition. Furthermore, Moller et al. discloses the use of electrochemical deposition (ECD) in discussing their preferred embodiment. The ECD process is defined as "a process for deposition of metal/metal alloys or metal compounds on a base material (mandrel) by electrolysis from aqueous solution, organic solution or salt melts." Col. 7, lines 38-41. Those skilled in the art would understand that electrochemical deposition is starkly different from the claimed vacuum deposition processes, which does not rely upon any electrolysis from solution or salt melts. Accordingly, Moller et al. fails to anticipate the claimed invention.

The rejection of claims 14-17, 19 and 21-22 under section 102(e) over Reed et al. should be withdrawn because it fails to disclose all the elements of the claimed invention. Since Reed et al. fails to disclose every element it cannot anticipate the present invention. Reed et al. is

concerned with a stent apparatus that includes a probe on its surface and only generally mentions the deposition of metal, including using a combination of evaporation, sputtering and electroplating, and electroless deposition methods, but fails to teach vacuum deposition for fabricating a radially expandable stent. In support of the various contemplated deposition methods, Reed et al. simply cites to S.K. Ghandhi, "VLSI Fabrication Principles," John Wiley and Sons (1981) and S.M. Sze, "Semiconductor Sensors," John Wiley and Sons (1994), but fails to specifically teach vacuum deposition. The sections of the specification cited by the Examiner fail to support the allegation that Reed et al. does disclose the vacuum deposition method. Col. 9, lines 44-54 only discloses RF-magnetron sputtering or chemical vapor deposition methods for coating a silicon surface with a sacrificial layer. Col. 10, lines 10-12 and 66-67 discuss recoating silicon wafers with a sacrificial layer and metal layers and coating a mandrel with a conformal layer with a list of techniques: electroplating, electroless deposition, evaporation, or others. These disclosures fail to disclose a vacuum deposition method for depositing the stent forming material. Since all the elements of the claimed invention are not present in Reed et al., it fails to anticipate the claimed invention.

Based on all of the foregoing arguments, Applicants respectfully request the Examiner to withdraw the 35 U.S.C. §102 rejections based on the cited art.

II. The Provisional Rejection of Claims 14-23 for Obviousness-Type Double Patenting Over Claims 1-10 of Copending Application No. 09/745,304 Should be Withdrawn.

Applicants note the provisional rejection and, upon indication of allowable subject matter, will substantively address this provisional rejection.

III. The Objection to Claims 17-23 under 37 CFR 1.75(c) Is Traversed By the Amendments

Applicant respectfully submits that the Amendments presented to claims 17-23 traverse the basis for the objection under 37 CFR 1.75(c). All the amendments made herein are non-substantive in nature and are made only to clarify the relationships between the claims and place the claims in proper dependent form. No new matter is added because of these amendments.

IV. New Claims 29-38 Patentably Define Over the Art Of Record

Claims 29-38 define the inventive method as including vacuum deposition onto a substrate having a continuously curved exterior surface. Thus, the substrate may be cylindrical or tubular, or have other geometric shaped in which there is a continuously curved exterior deposition surface. Neither the Roth nor the Moeller reference teaches deposition onto a curved substrate surface. Reed does, however, suggest that fabricating a "cylindrical mandrel with probes on the surface" is possible by "employing micro EDM techniques on a metal tube or rod" then the "mandrel is coated (by electroplating, electroless deposition, evaporation or other techniques) by a conformal layer of metal." Col 10, lines 62 to Col 11, line 1. Reed also further suggests that "Holes for the lattice pattern 10, can be made with EDM, or a selective deposition technique could be used which results in metal deposition only where it is wanted. After dissolving or otherwise removing the mandrel, the apparatus is released and ready for use." Col 11, lines 1-5.

First and foremost, Reed refers to the disparate deposition technologies of electroplating and electroless deposition, both of which are wet-processes conducted in liquid bath environments like Moeller, or evaporation, which is a sublimation process conduced in a vacuum or other "techniques" which could be understood to include both liquid or vacuum techniques known in the semiconductor arts. Reed's teaching, therefore, is nothing more than a shotgun approach to suggesting the possibility that some type of deposition process ***may*** work, without providing any guidance as to how to apply any specific technique, the conditions under which a specific technique ***might*** be followed, or the predictability of success of any particular deposition method for obtaining "these apparatus" referred to in Col. 10, line 62 of Reed. Other than these extremely generally statements, there Reed is devoid of any teaching that would suggest to one of ordinary skill in the art that the resulting endoluminal stent was capable of radial expansion by geometric deformation as presently claimed.

At most, Reed may provide to one of skill in the art the suggestion to try. However, in order to fabricate by vacuum deposition onto a cylindrical substrate an endoluminal stent which is capable of radial expansion by geometric deformation, as Applicant's have accomplished and as demonstrated to the Examiner's at the Examiner's Interview on October 3, 2002, would unquestionably require a significant amount of undue experimentation to achieve the requisite material properties necessary for a radially expandable device.

Moreover, while Reed may offer a suggestion to try vacuum deposition of a stent-forming onto a cylindrical mandrel, Reed fails to teach or even remotely suggest that the material properties of the resulting endoluminal stent could be controlled during vacuum deposition in such a manner as to yield a radially expandable stent.

Accordingly, Applicant respectfully submits that neither Roth, Reed or Moeller anticipate the invention claimed in new claims 29-37, or in amended claims 14-22 for purposes of 35 U.S.C. §102, nor do Roth, Reed nor Moeller, taken alone, or in combination render the presently claimed invention obvious under 35 U.S.C. §103 for the reasons stated above.

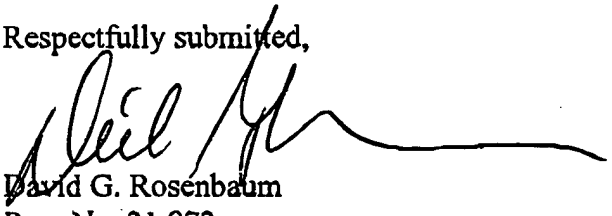
Summary

According to the arguments presented above, the applicants respectfully submit that the cited references fail to anticipate or render obvious the present invention and submit that pending claims 17-23 and new claims 29-38 are allowable over the art cited and that of record

This Response is being timely filed as it is being filed along with a three-month extension and appropriate fees.

Should the Examiner require any further information or wish to discuss any aspect of this Response, the Examiner is encouraged to telephone the undersigned at the telephone number set forth below.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES

In the claims:

17. The method according to Claim [13]14, further comprises the step of depositing a sacrificial layer of a material on to the substrate prior to step (b).

18. The method according to Claim [13]14, wherein step (b) is conducted by ion beam-assisted evaporative deposition.

19. The method according to Claim [13]14, wherein step (b) is conducted by sputtering.

20. The method according to Claim [19]18, wherein the ion beam-assisted evaporative deposition is conducted in the presence of an inert gas.

21. The method according to Claim [13]14, wherein the substrate is a cylindrical substrate.

22. The method according to Claim [13]14, wherein the substrate is a planar substrate.

Claim 29 (New) A method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter and having a plurality of first structural elements defining a longitudinal axis of the stent and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent, comprising the steps of:

a. providing a substrate having a generally continuously curved exterior surface capable of accommodating metal deposition thereupon;
b. depositing a stent-forming metal onto the exterior surface of the substrate by vacuum deposition;
c. forming in the stent-forming metal the plurality of first structural elements and the plurality of second structural elements interconnecting adjacent pairs of first structural elements; and

d. removing the substrate from the endoluminal stent formed thereupon, thereby obtaining an endoluminal stent capable of radially expanding from a first diameter to a second diameter by geometric deformation of at least some of the plurality second structural elements.

Claim 30 (New) The method of Claim 29, wherein the vacuum deposition of step (b) further comprises sputter deposition.

Claim 31 (New) The method of Claim 29, wherein the stent-forming metal of step (b) further comprises a shape memory alloy.

Claim 32 (New) The method of Claim 31, wherein the shape memory alloy further comprises a binary nickel-titanium alloy.

Claim 33 (New) The method of Claim 29, wherein the stent-forming metal of step (b) is selected from the group consisting of elemental titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, and nitinol and stainless steel.

Claim 34 (New) The method of Claim 29, wherein step (a) further comprises the step of providing a substrate having a generally cylindrical exterior surface for accommodating metal deposition thereupon.

Claim 35 (New) The method of Claim 29, wherein step (b) further comprises the step of controlling heterogeneities in the stent-forming metal during vacuum deposition.

Claim 36 (New) The method of Claim 35, wherein the step of controlling heterogeneities further comprises the step of controlling at least one of grain size, grain phase, grain material composition, stent material composition and surface topography during vacuum deposition.

Claim 37 (New) The method of Claim 35, wherein the step of controlling heterogeneities further comprises the step of defining polar and non-polar binding sites for binding blood plasma proteins.

Claim 38 (New) The method of Claim 29 wherein step (b) further comprises the step of controlling at least one of fatigue life, corrosion resistance, corrosion fatigue, inter- and intra-granular precipitates, bulk material composition, bulk and surface material properties, radioopacity, transverse geometric profile of the endoluminal stent, Z-axis thickness, X-Y-axis surface area of the first and second structural elements, thereby affecting at least one of longitudinal flexibility, hoop strength, radial expansion behavior and profile of the endoluminal stent.